

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Boehringer Ingelheim Vetmedica, Inc., to Alpharma, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506-2002, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 39-077 for CSP (chlortetracycline, sulfathiazole, penicillin) 250 and CSP 500 Type A medicated articles to Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024. Accordingly, the agency is amending the regulations in 21 CFR 558.155 to reflect the change of sponsor.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

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NFR1

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

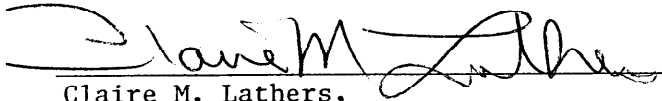
Authority: 21 U.S.C. 360b, 371.



§ 558.155 [Amended]

1. Section 558.155 *Chlortetracycline, sulfathiazole, penicillin* is amended in paragraphs (a)(1) and (a)(2) by removing "Nos. 000010 and 046573" and by adding in its place "No. 046573".

Dated: 2/22/02
February 22, 2002.



Claire M. Lathers,
Director,
Office of New Animal Drug
Evaluation,
Center for Veterinary Medicine.
[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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